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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,021	COLE ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *27,28,30-42,50-56,58 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,15-17,24-26,44 and 45* is/are rejected.

7)☒ Claim(s) *12-14,18-23,26,29,43,46-49 and 57* is/are objected to.

8)☒ Claim(s) *1-59* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1October2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 23 July 2007, is acknowledged.

Applicants elect, with traverse, Invention I, claims 1-26, 29, 43-49, and 57, drawn to transformed *M. bovis* BCG strain, and further proviosionally elect species SEQ ID NO:1.

Applicant's traversal is on the grounds that the requirement is improper because the special technical technical feature is all or part of SEQ ID NO:1. This is not found persuasive because of the reasoning put forth in the original rejection, i.e., the DNA listings in the claims are well known in the art as evidenced by the prior art discussed in the International Preliminary Examination Report. Thus, the only special technique features are the actual transformed mycobacteria

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-59 are pending. Claims 27-28, 30-42, 50-56, and 58-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 12-14, 18-23, 29, 43, 46-49, and 57 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from a multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

2. Claims 1-11, 15-17, 24-26, 44, and 45 are under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Page 1, line 10, "regions are known as RD5 as disclosed" should be "regions known as RD5 is disclosed"; line 18, "*Mycobacteria*" is only partially italicized.

Page 2, line 1, "Mycobacteria" should be in italics; line 9, "antigenes" should be "antigens".

Page 6, line 24, "In an another" should be "In another".

Page 8, line 24, "promoter" should not be underlined.

Page 15, line 3, "*the*" should not be in italics.

Page 23, line 3 is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 24, line 14 is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 25, line 13, "Immunisation" should be "Immunization"; line 15, "immunised" should be "immunized".

Page 26, line 2, "immunisation" should be "immunization"; line 14, what is a Wilcoxon "rang" sum test?

Page 27, lines 23-24 is objected to because it contains embedded hyperlinks and/or other form of browser-executable codes. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

Page 28, line 8, "centre" should be "center"; lines 19, 21, and 25, "immunised" should be "immunized".

Page 29, line 2, "**c**" should be "**C**"; line 3, "immunisation" should be "immunization"; line 18, "analysed" should be "analyzed".

Page 30, line 6, two instances of "immunised" should be "immunized"; line 19, "stabilisation" should be "stabilization"; line 25, "characterisation" should be "characterization"; line 27, "dimerisation" should be "dimerization".

Page 31, line 2, "catalysed" should be "catalyzed".

Page 34, line 4, "immunisation" should be "immunization".

Page 37, lines 8-9 is objected to because it contains embedded hyperlinks and/or other form of browser-executable codes. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

Page 40, lines 20 and line 24, "figure" should be "Figure".

Page 41, line 10, "figure" should be "Figure".

Page 43, lines 14 and line 27, "figure" should be "Figure".

Page 49, line 3, "genes is" should be "genes are".

Page 54, line 13, what is meant by "hypothesis[20]"?

Page 55, line 4, what is "IFN-[]"? Lines 6 and 11, "Fig" should be "Fig."

Page 58, lines 6 and 11, "immunised" should be "immunized".

Page 59, line 3, what is meant by "tuberculosis[]*Nature*"?

Page 61, line 4, "centre" should be "center"; line 25, "dimerisation" should be "dimerization".

Page 63, line 22, what is meant by "impotence[]*Nature*"?

Appropriate correction is required.

Deposit Requirements

Applicant's referral to the deposit of the *E. coli* strains designated I-2831 and I-2832 in claim 24 and page 18, lines 22-25 of the specification is an insufficient assurance that all

required deposits have been made and all the conditions of 37 CFR §§1.801-1.809 have been met.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each nation. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §§1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) the name and address of the depository,

2) the name and address of the depositor,

3) the date of deposit,

4) the identity of the deposit and the accession number given by the depository,

5) the date of the viability test,

6) the procedures used to obtain a sample if the test is not done by the depository, and

7) a statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the strains described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundeck, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §§1.801-1.809 for further information concerning deposit practice.

Drawings

4. Figures 3A, 3B, and 3C are objected to under 37 CFR 1.83(a) because they fail to show "grey", "light grey", "middle grey", and "dark grey" as described in the specification, page 25, lines 1-9. All the bars look as "black" or "stipled".

Figure 4C is objected to under 37 CFR 1.83(a) because it fails to show "middle grey", "light grey", and "white" as described in the specification, page 26, lines 1-7. All the bars look as "black" or "stipled".

Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from

the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claim 26 is objected to because of the following informality: "ca" in line two should have a period immediately following, i.e., "ca.". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a strain of transformed *M. bovis* BCG which has integrated "all or part of the fragment, named RD1-2F9, of 31808 bp of DNA originating from *M.*

tuberculosis"....."as shown in SEQ ID No 1". The term "as shown in" is unclear. Recommended language is "designated as SEQ ID No 1".

8. Claims 4-11, 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a transformed *M. bovis* BCG "which has integrated a portion of DNA originating from" a source mycobacterium, "which comprises at least" one, two, three, or more genes selected from a group.

It is unclear if the portion comprises a listed gene or if the whole *M. tuberculosis* comprises the "at least" genes and the integrated portion if from any the entire genome of the source mycobacterium.

9. Claims 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to *M. bovis* strains which have integrated a cosmid herein referred to a RD1-2F9 and RD1-AP34 contained in *E. coli* strains. It is unclear if each of the two deposited strains comprise both cosmids or if one cosmid is contained within one deposited strain and the other cosmid is contained within the other deposited strain.

10. Claims 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that the insert "which corresponds to" a fragment of the *M. tuberculosis* H37Rv genome. It is unclear what is meant by "corresponds to".

11. Claims 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that the insert "covers" a region of the *M. tuberculosis* genome. It is unclear what is meant by "covers".

12. Claims 44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from non-elected claims.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-11, 15-17, 44, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahairas et al (*J. Bacteriol.*, 178(5):1274-1282, 1996).

The claim are drawn to transformed *M. bovis* strains comprising all or a portion of SEQ ID NO:1.

Mahairas et al teaches transformed *M. bovis* BCG which comprise all or part of the entire RD1 region of *M. tuberculosis* which encompasses the instant SEQ ID NO:1 (abstract; Table 1; section **Materials and Methods**, pages 1275-1276; page 1280, right column, 2nd paragraph).

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

September 28, 2007